

Message

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Sent: 2/23/2021 12:52:22 PM
To: Kent Fothergill (fothergill.kent@epa.gov) [fothergill.kent@epa.gov]
Subject: FW: FYI -- California Notice 2021-02: Semiannual Report Summarizing the Reevaluation Status
Attachments: ATT00001.txt

FYI --- it caught my attention that 2nd gen rodenticides made the list...

From: Becker, Jonathan <Becker.Jonathan@epa.gov>
Sent: Tuesday, February 23, 2021 7:51 AM
To: OPP BEAD BAB <OPP_BEAD_BAB@epa.gov>
Subject: FYI -- California Notice 2021-02: Semiannual Report Summarizing the Reevaluation Status

Chloropicrin, cyfluthrin, neonicotinoids, 2nd generation anticoagulant rodenticides,

From: canote-bounces@pestreg.cdpr.ca.gov <canote-bounces@pestreg.cdpr.ca.gov> **On Behalf Of** CANote@CDPR
Sent: Monday, February 22, 2021 8:39 PM
To: 'canote@pestreg.cdpr.ca.gov' <canote@pestreg.cdpr.ca.gov>
Subject: California Notice 2021-02: Semiannual Report Summarizing the Reevaluation Status

California regulations require the Department of Pesticide Regulation (DPR) to investigate reports of possible adverse effects to people or the environment resulting from the use of pesticides. Reevaluation of a registered pesticide is required if a significant adverse impact occurred, or is likely to occur, from its use.

Title 3 of the California Code of Regulations (3 CCR) section 6221, specifies several factors under which DPR may initiate a reevaluation: (a) public or worker health hazard, (b) environmental contamination, (c) residue over tolerance, (d) fish or wildlife hazard, (e) lack of efficacy, (f) undesirable phytotoxicity, (g) hazardous packaging, (h) inadequate labeling, (i) disruption of the implementation or conduct of pest management, (j) other information suggesting a significant adverse effect, (k) availability of an effective and feasible alternative material or procedure that is demonstrably less destructive to the environment, and (l) discovery that data upon which a registration was issued is false, misleading, or incomplete. Often, an ongoing DPR pesticide review triggers a reevaluation. Reevaluation triggers also include data or information received from state and county pesticide use surveillance and illness investigations, pesticide residue sample analyses, environmental monitoring activities, and issues that may concern other state or federal agencies.

When a pesticide enters the reevaluation process, DPR reviews existing data and may require that registrants provide additional data to characterize the nature and extent of the potential hazard and identify appropriate mitigation measures if needed.

DPR concludes reevaluations in a number of different ways. If the data demonstrates use of the pesticide presents no significant adverse effects, DPR concludes the reevaluation without additional mitigation measures. If additional mitigation measures are necessary, DPR will place appropriate restrictions on the use of the pesticide to mitigate the potential adverse effect. If the adverse impact cannot be mitigated, DPR cancels or suspends the registration of the pesticide product.

This report complies with the requirement of 3 CCR section 6225, which requires DPR to prepare a semiannual report describing pesticides reevaluated, under reevaluation, or for which factual or scientific information was received, but no reevaluation was initiated. The report contains two sections:

- I. *Formal Reevaluations*--initiated when an investigation indicates a significant adverse impact has occurred or is likely to occur; and,
- II. *Preliminary Investigations (Evaluations)*--initiated when DPR receives possible adverse impact data or information resulting from the use of a product and/or active ingredient, but no formal reevaluation has been initiated.

CALIFORNIA NOTICE 2018-01

California Notice 2018-01, titled Expanding Use of Pesticide Products under Reevaluation, was issued on January 3, 2018. In accordance with this notice, DPR will not act upon an Application for Pesticide Registration or an Application to Amend Pesticide Product if it is relevant to the concern that prompted the reevaluation. The notice affects new products, supplemental distributor registrations, amendments, Special Local Needs, and Experimental Use Permits. DPR will evaluate Emergency Exemption requests on a case-by-case basis if a pest management or public health need arises. When DPR completes the reevaluation, DPR will be able to, in light of the reevaluation determination, consider the Application for Pesticide Registration or Application to Amend Pesticide Product.

To view the notice, please visit DPR's California Notices to Stakeholders Web page at <https://www.cdpr.ca.gov/docs/registration/canot/camenu.htm>.

FORMAL REEVALUATION

DPR initiates formal reevaluation when an investigation indicates a significant adverse impact has occurred or is likely to occur. Each reevaluation is summarized with regard to the following four areas: (1) *Basis and Scope*, (2) *Data Requirements* (if any), (3) *Summary* (e.g., protocol development, study/data submission and evaluation, DPR analysis papers, risk assessments), and (4) *Mitigation Efforts and Status*.

CHLOROPICRIN - 35 Products

Basis and Scope

In October 2001, DPR placed pesticide products containing the active ingredient chloropicrin into reevaluation. The reevaluation is based on air monitoring data, which found that air concentrations at some distances from treated greenhouses exceeded the National Institute for Occupational Safety and Health reference exposure limit and the Occupational Safety and Health Administration permissible exposure limit of 100 parts per billion (ppb), averaged over an eight-hour period. In addition, DPR found that data submitted under the Birth Defects Prevention Act indicated chloropicrin has the potential to cause adverse health effects at low doses.

Data Requirements

Under this reevaluation, DPR required registrants of pesticide products containing the active ingredient chloropicrin to conduct and submit data on various worker exposure and air quality monitoring studies from field and greenhouse applications. In August 2005, DPR completed its review of the required monitoring data and began work on a risk assessment of chloropicrin uses as part of the reevaluation process to mitigate potential adverse effects at low concentrations. In January 2015, DPR notified chloropicrin registrants of a new data requirement to determine if chronic exposure to chloropicrin presents a carcinogenic hazard requiring mitigation. In July 2015, DPR established a mechanistic study data requirement for the scientific assessment of the carcinogenic hazard of chloropicrin based on evaluation of submitted and other available data and information.

Summary

In February 2010, DPR completed a risk characterization document (RCD) for chloropicrin as a toxic air contaminant (TAC). The RCD analyzed the risks associated with potential exposures to residents and bystanders from ambient and offsite air concentrations of agricultural use chloropicrin products. The California Air Resources Board's Scientific Review Panel on Toxic Air Contaminants completed its peer review of the document in April 2010. In December 2010, DPR filed a regulation listing chloropicrin as a TAC. Also in December 2010, based on the TAC risk assessment, DPR issued a risk management directive (RMD) to address resident and bystander exposures identified by the TAC evaluation. This RMD determined that the appropriate regulatory target level to restrict acute exposure to chloropicrin is 73 ppb averaged over an eight-hour period. Chloropicrin was designated as a TAC effective January 8, 2011, and DPR initiated development of use restrictions following TAC procedures specified in state law. In November 2012, DPR completed its comprehensive RCD for chloropicrin, which included dietary and occupational exposure scenarios.

In July 2015, DPR established a new mechanistic data requirement to attain more information on the potential carcinogenicity of chloropicrin. On several occasions, the Chloropicrin Manufacturers' Task Force (CMTF), which represents chloropicrin registrants, met with DPR to discuss technical elements, methodology, and study protocol. In June 2016, DPR accepted the CMTF protocol for the mechanistic study titled, *Identification of mouse lung target cell type and target respiratory region for effects following nose-only inhalation exposure to chloropicrin vapor*. In December 2016, DPR met with CMTF to discuss study timeline, logistics, technical challenges, an extension request from CMTF, and an additional information request from DPR.

In March 2017, CMTF provided additional information and an update on the initiation of the study. In April 2017, CMTF provided a progress report. In May 2017, DPR granted CMTF's extension request establishing a new final study submission due date of December 31, 2020, and added the requirement to submit quarterly interim reports. In 2018 and 2019, CMTF submitted the required quarterly interim reports.

In March 2019, DPR met with CMTF to discuss the on-going study. During the meeting, CMTF recommended DPR review and consider public literature, which DPR received in May 2019. DPR scientists will incorporate relevant public literature into their review of the completed study. In October 2019, in response to a question from DPR scientists, CMTF submitted clarification on the protocol.

CMTF submitted two draft amendments to the Chloropicrin Mechanistic Study Protocol, one in December 2019, and the other in January 2020. CMTF and the Study Director met with DPR to provide clarification on the draft protocol amendments in January 2020. Based on the clarification provided, DPR found the draft protocol amendments acceptable and concurs that the revisions will result in an improved study protocol. Additionally, a minor protocol amendment to the laboratory location was submitted and approved in March 2020.

In January and May 2020, CMTF submitted the required quarterly interim reports. In the May 2020 interim report, CMTF notified DPR of laboratory closure due to COVID-19. Subsequently, CMTF formally requested an extension for submission of the study based on uncertainties in laboratory reopening. In early June 2020, DPR granted CMTF's extension request and established a new final study submission due date of June 30, 2021.

In September and December 2020, CMTF submitted the required quarterly interim reports. CMTF has requested further study extension in light of continued laboratory closure due to COVID-19. DPR and CMTF have plans to meet in January 2021 to discuss the new request for study extension and anticipated 2021 timelines.

Mitigation Efforts and Status

During the course of this reevaluation, the U.S. EPA developed label mitigation measures under its Reregistration Eligibility Decision for products containing chloropicrin. These soil fumigant label measures require users to prepare site-specific Fumigant Management Plans and are intended to mitigate unacceptable exposures to workers, residents, and bystanders. The measures were implemented in two phases and went into effect in December 2010 and December 2012. The measures added more restrictions, prohibitions, human health protection language, and information on the product label.

In May 2013, DPR proposed mitigation measures designed to protect bystanders and residents from acute exposures to chloropicrin for public comment. DPR developed these mitigation measures using U.S. EPA's label changes as the foundation for mitigating offsite exposures. DPR proposed additional restrictions beyond labeling and regulation to protect residents and bystanders including additional buffer zones, restriction on buffer zone credits, acreage limits, time periods between applications with overlapping buffer zones, emergency preparedness and response, and notice of intent requirements. DPR developed the proposed mitigation measures in consultation with the California Air Resources Board, the air pollution control districts, and the county agricultural commissioners, as required by California Food and Agricultural Code (FAC) section 14024(a). In addition to consulting with state and local agencies required by law, DPR discussed early mitigation concepts with worker advocate groups and registrants. DPR also submitted its analysis entitled, "Evaluation of Chloropicrin as a Toxic Air Contaminant, Part B Human Health Assessment" for scientific peer review. DPR received and responded to comments from several thousand people and three external scientific peer reviewers.

In early January 2015, DPR issued "Control Measures for Chloropicrin: Control of Resident and Bystander Acute Exposure from Soil Fumigation Applications." The controls are intended to reduce risk from acute exposures to residents and bystanders that might occur near fields fumigated with products containing chloropicrin. Also in January 2015, DPR presented the chloropicrin mitigation measures to the Pesticide Registration and Evaluation Committee (PREC) and members of the public. In April 2015, DPR issued interim recommended restricted material permit conditions for field fumigants containing chloropicrin. In February 2017, DPR issued revised interim permit conditions developed to mitigate hazards of offsite movement of field fumigation applications of chloropicrin. More information on human health risk assessment and mitigation for chloropicrin is available on DPR's Human Health Risk Assessment and Mitigation Web page at http://www.cdpr.ca.gov/docs/whs/active_ingredient/chloropicrin.htm.

In March 2020, U.S. EPA issued its interim registration review decision for products containing chloropicrin. The interim decision includes labeling changes such as general updates to the glove statement, clarification on shade houses, soil sealing, and application rates on the product label. DPR continues to monitor amended pesticide product registrations to ensure labeling compliance.

CYFLUTHRIN - 24 Products

Basis and Scope

In May 1998, DPR placed pesticide products containing the active ingredient cyfluthrin into reevaluation. The reevaluation is based on DPR's investigations of a May 1997 respiratory irritation outbreak reported among orange harvesters exposed to cyfluthrin residues and other related pesticide illness reports. As part of the investigation, DPR's Worker Health and Safety Branch conducted two separate inhalation-monitoring studies in orange groves during orange harvest. As dust and pollen are a part of the normal working environment, DPR determined that additional variables in the work environment led to the workers' respiratory irritation symptoms. DPR compiled the results in its monitoring study titled, *Health and Safety Report HS – 1765*, which found a probability that cyfluthrin, applied close to harvest, led to the symptoms experienced.

Data Requirements

Under this reevaluation, DPR required registrants of pesticide products containing the active ingredient cyfluthrin to provide (1) a respiratory irritation study, (2) a worker exposure study, and (3) monitoring data for structural applications. In October 2001, the primary manufacturer submitted two worker exposure studies regarding hand harvesting of oranges and sweet corn, four indoor exposures studies, and a study titled, *Study on the RD₅₀ Determination in Rats*. Based on this data, DPR determined structural monitoring data was no longer required.

However, during the course of this reevaluation, DPR determined it had insufficient data regarding worker exposure during the hand harvesting of sweet corn. As a result, in February 2002, DPR required a worker exposure study be conducted during the harvesting of sweet corn. The results of the study were submitted to DPR in October 2004.

Summary

In 2006, DPR determined a comprehensive exposure assessment was necessary for cyfluthrin. In September 2008, DPR completed an Exposure Scoping Document for cyfluthrin intended to lay the groundwork for the risk assessment process. DPR completed review of cyfluthrin sweet corn hand harvester studies and the reevaluation is pending further assessment of the potential risks associated with the use of cyfluthrin. In August 2015, DPR completed its Summary of Toxicology Data document for chronic health effects on cyfluthrin.

Mitigation Efforts and Status

In January 2018, DPR issued a problem formulation document to initiate risk assessment. In February 2018, DPR presented the problem formulation document and initiation of the risk assessment for cyfluthrin to the PREC. U.S. EPA completed its registration review and released the draft human health risk assessment in May 2020 and the interim registration review decision in September 2020. If upon completion of the risk characterization, DPR concludes that use of cyfluthrin poses a risk to workers, DPR will proceed with mitigation. More information on the human health risk assessment for cyfluthrin and additional resources are available on DPR's Human Health Risk Assessment and Mitigation by Active Ingredient Web page at http://www.cdpr.ca.gov/docs/whs/active_ingredient/cyfluthrin.htm.

NEONICOTINOIDS (NITROGUANIDINE INSECTICIDES) - 215 Products

Basis and Scope

In February 2009, DPR placed certain pesticide products containing the active ingredients imidacloprid, thiamethoxam, clothianidin, and dinotefuran into reevaluation. The reevaluation is based on an adverse effects disclosure involving the active ingredient imidacloprid. DPR's evaluation of the adverse effects data noted two critical findings: (1) high levels of imidacloprid in leaves and blossoms of treated plants and (2) increases in residue levels over time. Thiamethoxam, dinotefuran, and clothianidin are in the same chemical family as imidacloprid, known as the nitroguanidine insecticide class of neonicotinoids, and have similar properties and characteristics (e.g., soil mobility, half-lives, and toxicity to honey bees).

Data Requirements

Under this reevaluation, DPR required registrants of pesticide products containing the active ingredients imidacloprid, thiamethoxam, clothianidin, and dinotefuran to provide the following data for each active ingredient: (1) LC₅₀ (acute), categorized as a Tier I study, on honey bees, starting at the larval stage through emergence; and (2) field-based residue studies in pollen, nectar, and leaves from specific agricultural orchard and row crops. For field-based residue data requirements, DPR's Pesticide Use Reporting database was used to determine the crops of focus for each active ingredient. During the course of this reevaluation, initial field residue data provided were found to be inconclusive and did not involve "worst-case" scenarios, i.e., a residue

study conducted at the permitted California maximum application rate and the minimum reapplication interval. DPR modified its residue study strategy to require controlled applications at the highest maximum application rate per year for two consecutive years. For certain commodities, DPR required these two-year prescriptive residue studies of imidacloprid, thiamethoxam, clothianidin, and dinotefuran registrants.

Additionally, U.S. EPA requires higher tier honey bee toxicity studies and additional field-based residue studies for their reevaluation of neonicotinoids, which are shared with DPR and the Pest Regulatory Management Agency (PMRA) Health Canada. A Tier II study, or a feeding study, exposes bee colonies to known concentrations of a pesticide and examines the chronic effect. A Tier III study, or full field study, is a field-level study that looks at long-term effects under environmentally realistic exposure conditions.

Summary (by Active Ingredient)

Imidacloprid: In September 2009, DPR notified registrants of products containing the active ingredient imidacloprid of the LC₅₀ and field residue study data requirements. DPR required residue data on the following eight commodities: almonds, citrus, cotton, cucurbits, fruiting vegetables, pome fruit, strawberries, and later, also required data on stone fruits. Rather than conduct a residue study for almonds, imidacloprid registrants removed use on almonds from their labels, beginning in January 2011.

In May 2011, DPR received final reports for residue studies conducted on citrus, cotton, and tomato. Upon review of the submitted reports, DPR found both the cotton and tomato studies to be unacceptable because they did not represent worst-case scenarios. As a result, in March 2012, DPR expanded the crops required to include stone fruit, and required two-year prescriptive residue studies representing worst-case scenarios for cotton, tomatoes, pome fruit, and stone fruit.

In March 2012, DPR received a final report on chronic toxicity effects to larval honey bees. In April 2012, the primary manufacturer submitted additional studies on citrus. In December 2012, DPR received final reports on strawberry and melon. In December 2014, DPR received a final report on chronic toxicity effects to adult honey bees and received U.S. EPA-required residue data on blueberry, citrus, corn, cotton, stone fruit, and rotational white clover used as forage. In January and April 2016, DPR received final reports on cotton, tomatoes, apples, and cherries. In March and July 2017, DPR received U.S. EPA-required full field data on cotton and pumpkins.

Thiamethoxam: In September 2009, DPR notified registrants of products containing the active ingredient thiamethoxam of the LC₅₀ and field residue study data requirements. DPR required residue data on the following eight commodities: cucurbits, fruiting vegetables, pome fruit, strawberries, and later, on almonds, citrus, cotton, and stone fruit.

In March 2011, the primary manufacturer requested a waiver for the residue study requirement on pome fruit and strawberries due to limited California field applications of thiamethoxam in 2009 and 2010. DPR granted a waiver for the residue study on pome fruit. In January 2012, the primary manufacturer submitted final reports for residues in tomatoes and acute toxicity effects to larval honey bees.

In October 2012, DPR expanded the required crops to include almond, citrus, cotton, and stone fruit. In addition, DPR required two-year prescriptive residue studies for strawberry, almond, citrus, cotton, and stone fruit. In January 2013, DPR received a final report on cucurbits (cucumbers). In February 2013, rather than conduct a residue study for almonds, thiamethoxam registrants removed use on almonds from their labels. In December 2015, DPR received final reports on cotton and stone fruit (cherry, peach, and plum), as well as U.S. EPA-required residue data on cranberry, cucumber, pepper, tomato, and soybean treated seed. In March 2016, DPR received a final report on a voluntary orange study and U.S. EPA-required residue data on citrus. In March and July 2017, DPR received final reports on citrus and strawberry, as well as U.S. EPA-required residue data on tomato, pumpkin, melon, corn, and apple. In November 2017, DPR received a final report on chronic

toxicity effects to adult honey bees, an amended final report on cotton, and U.S. EPA-required residue data on sweet orange and blueberry. In April 2018, DPR received amended U.S. EPA-required residue data on citrus.

Clothianidin: In September 2009, DPR notified registrants of products containing the active ingredient clothianidin of the LC₅₀ and field residue study data requirements. DPR required residue data on the following five commodities: almonds, cucurbits, fruiting vegetables, pome fruit, and stone fruits. In November 2009, the clothianidin primary manufacturer requested, and was granted, a waiver for the residue study on pome fruit due to limited use in California. In February 2012, the primary manufacturer submitted a final report on chronic toxicity effects to larval honey bees.

In May 2013, DPR required two-year prescriptive residue studies for almond, cucurbit, fruiting vegetable, and stone fruit. In October 2015, DPR received a final residue report on cotton. In April and May 2015, DPR received a final report on pumpkins and U.S. EPA-required residue data on citrus and cucurbits. In lieu of conducting the residue studies on fruiting vegetables, clothianidin registrants removed fruiting vegetables from their labels. From March to July 2016, DPR received U.S. EPA-required residue data on cotton, pumpkin, potato, as well as additional residue data on cucurbit and citrus. In February 2017, DPR received a final residue study report on almonds, a final report on chronic toxicity effects to adult honey bees and received U.S. EPA-required residue data on corn, grapevines, apples, and melon. From March 2017 to March 2018, DPR received additional final reports on chronic toxicity effects to adult honey bees and submissions of U.S. EPA-required residue data on soybean treated seed, peach, and additional residue studies on corn and citrus.

Dinotefuran: In September 2009, DPR notified registrants of products containing dinotefuran of the LC₅₀ and field residue study data requirements. DPR required residue data on the following three commodities: cotton, cucurbits, and fruiting vegetables. In response, the primary manufacturer submitted data and information, including limited use data, for DPR review and consideration.

In March 2012, the primary manufacturer provided DPR with reports evaluating foraging honey bees and hives after exposure to dinotefuran, and acute toxicity effects to honey bee data. In October 2015, DPR received a final report on acute larval toxicity effects to honey bees. During the report period, DPR received final residue reports on cucurbits (cucumber) and fruiting vegetables (tomatoes). In February and March 2016, DPR received U.S. EPA-required residue data on potato, pumpkin, cherry, and cranberry. In February 2017, DPR received a final residue report on cotton, chronic toxicity effects to adult honey bees, and U.S. EPA-required residue data on stone fruit, bell pepper, cucurbit, cantaloupe, and blueberry.

Mitigation Efforts and Status

In April 2010 and December 2012, imidacloprid and thiamethoxam registrants, respectively, agreed to remove use on almonds from all product labels in California. DPR considered this an important mitigation step in pollinator protection since almond orchards require a large number of pollinators.

In August 2013, U.S. EPA notified registrants of neonicotinoids of new labeling requirements for all products having outdoor foliar use directions (except granular formulations). This required registrants to include prescribed bee protective language on their product labels by the 2014 agricultural-use season for both existing and new product registrations. In November 2013, DPR required registrants to submit amended labels to California within 30 days of U.S. EPA acceptance. DPR completed its review of the U.S. EPA required label changes. Any of these products sold in the California marketplace must contain the improved pollinator protective label language.

In June 2014, DPR, U.S. EPA, and PMRA Health Canada completed a collaborative document titled, *Guidance for Assessing Pesticide Risks to Bees*. In June 2014, a Presidential Memorandum creating a federal strategy to promote the health of honey bees and other pollinators was signed. In January 2016, U.S. EPA released a preliminary pollinator risk assessment for imidacloprid, which was a collaborative effort between DPR, U.S.

EPA, and PMRA Health Canada. In January 2017, U.S. EPA released the preliminary pollinator risk assessments for thiamethoxam, clothianidin, and dinotefuran.

In July 2018, DPR issued the California Neonicotinoid Risk Determination and submitted it to the State Legislature in accordance with the requirements of California Food and Agriculture Code (FAC) section 12838. The risk determination report is a refined Tier II assessment built off of U.S. EPA's preliminary pollinator risk assessments and includes additional data that DPR received after U.S. EPA's preliminary pollinator risk assessments were issued. The determination report compares colony feeding study values to worst-case scenario residue values to determine risks to honey bees. After issuing the determination report, DPR received information identifying inconsistencies. Based on the newly available information, DPR issued an addendum to the California Neonicotinoid Risk Determination in January 2019. Additionally, in September 2018, DPR presented the risk determination report and the next steps required by FAC section 12838 to the PREC.

In January 2020, U.S. EPA issued their proposed interim registration review decisions (PIDs) for the four neonicotinoid active ingredients. Staff have assessed the PIDs to determine if any other considerations should be incorporated into the mitigation efforts.

In February 2020, DPR solicited formal scientific peer review on the documents that will be used to scientifically support mitigation decisions, including the California Neonicotinoid Risk Determination and addendum. The peer review was completed in June 2020, and DPR will document how the feedback will be incorporated into mitigation efforts.

In accordance with the requirement of FAC section 12838 for DPR to adopt necessary control measures to protect pollinator health, DPR has continued to review data and consult with experts and other stakeholders to help inform potential mitigation decisions. DPR contracted with the California Department of Food and Agriculture (CDFA) Office of Pesticide Consultation and Analysis to provide an economic analysis of various proposed mitigation alternatives.

In July 2020, DPR presented an overview of the next steps in the reevaluation and proposed mitigation plan for neonicotinoid uses on specific agricultural crops and crop groups to the PREC. In August 2020, DPR held stakeholder outreach webinars with Spanish interpretation to discuss the draft regulation proposal and solicit feedback. DPR posted copies of the mitigation proposal, the slides presented at the webinars, and recordings of the webinars on DPR's Neonicotinoid Reevaluation Web page linked below. Following the webinars, DPR held a comment period through September 11, 2020, to receive feedback from the public and stakeholders on the draft mitigation proposal. On August 13, 2020, DPR posted additional background information, including CDFA's draft economic analyses, and due to the complexity of the proposal and new materials, extended the comment period to October 11, 2020. On September 28, 2020, DPR provided further background information and extended the comment period to October 30, 2020.

DPR received over 9000 comments on the draft mitigation proposal, and staff are currently reviewing the comments received. DPR will use this feedback along with the U.S. EPA PIDs and peer review feedback to refine and update the regulation proposal as appropriate.

For more information on the reevaluation for neonicotinoids, please visit DPR's Reevaluation Web page at <http://www.cdpr.ca.gov/docs/registration/reevaluation/chemicals/neonicotinoids.htm>.

SECOND-GENERATION ANTICOAGULANT RODENTICIDES (SGARs) - 69 Products

Basis and Scope

Second-generation anticoagulant rodenticide (SGAR) products are those that contain the active ingredients brodifacoum, bromadiolone, difenacoum, and difethialone. DPR conducted a preliminary investigation of

unpublished wildlife incident data and mortality data and public literature submitted by CDFW and other sources on anticoagulant rodenticides and prepared a report on its findings.

DPR's preliminary investigation determined that despite the 2014 regulations that changed SGAR use patterns by restricting their purchase, sale, and use, reported rates of non-target wildlife exposure to SGARs had not decreased. Additionally, the investigation found evidence of possible population-level impacts among non-target wildlife in California due to statistically significant associations with SGAR exposure and sublethal impacts. The investigation indicates that non-target wildlife exposure may be significant due to the chemical characteristics of SGARs, which are known to have properties of high toxicity, persistence, and bioaccumulation. The investigation also notes that brodifacoum has relatively higher rates of exposure among non-target wildlife compared to other SGARs.

Based on the preliminary investigation, the DPR Director found that a significant adverse impact has occurred or is likely to occur from the use of SGARs and proposed to begin reevaluation. In November 2018, DPR issued its proposed decision to begin reevaluation for SGAR products containing the active ingredients brodifacoum, bromadiolone, difenacoum, and difethialone and allowed a 60-day comment period. DPR presented the proposed decision to begin reevaluation of SGARs to the PREC in January 2019 and to the Agricultural Pest Control Advisory Committee in March 2019.

On March 12, 2019, DPR issued its final decision to begin reevaluation for SGAR products containing the active ingredients brodifacoum, bromadiolone, difenacoum, and difethialone. The notice of final decision included a summary of the 17,234 comments received and provided response to relevant comments.

Data Requirements

Under this reevaluation, DPR required registrants of pesticide products containing the active ingredients brodifacoum, bromadiolone, difenacoum, and difethialone to (1) submit compliance proposals by May 2019, and (2) submit existing data related to non-target wildlife exposure by June 2019. Registrants of SGAR products containing brodifacoum, bromadiolone, and difethialone submitted the required compliance proposals and existing non-target wildlife exposure data.

In August 2020, DPR had companies identify efficacy data that could inform mitigation by demonstrating a lower concentration of active ingredient in the target pests, such as through reduced application rates, lowered concentration of the SGAR ingredient, and alternative bait timings. By November 2020, companies either submitted new data to DPR or identified relevant studies for review from previous submissions. DPR scientists continue to review the new company identified data, data on file, and public literature to form a basis for additional data requirements and mitigation.

Mitigation Efforts and Status

In place of submitting compliance proposals and data, registrants submitted voluntary cancellations for all three previously registered difenacoum products. As of May 2019, DPR no longer has any difenacoum products registered for use in California.

In July and December 2019, DPR met with rodenticide stakeholders to discuss non-regulatory mitigation strategies and on-going scientific studies on SGARs. In December 2019 and April 2020, a registrant voluntarily submitted for DPR's review and consideration information about studies they intended to conduct. In May 2020, DPR presented the status of the SGAR reevaluation and data review to the PREC. In August 2020, DPR met with rodenticide stakeholders to discuss the SGAR reevaluation and the data identification letter.

In September 2020, Governor Newsom signed Assembly Bill (AB) 1788 (Chapter 250, Statutes of 2020) to prohibit uses of SGARs due to their threat to mountain lions and other wildlife. AB 1788, which went into

effect January 1, 2021, prohibits the use of SGARs statewide subject to limited exceptions until the DPR Director certifies (1) the department's completion of its reevaluation of SGARs, and (2) the department's development, in consultation with the California Department of Fish and Wildlife (CDFW), and adoption of any additional use restrictions necessary to protect wildlife.

In December 2020, DPR met with CDFW to discuss the SGAR reevaluation and consultation process. DPR will continue to work with stakeholders, including SGAR researchers, to facilitate discussions of potential mitigation strategies, and to incorporate the evaluation of current public literature into the reevaluation.

For more information on the reevaluation for SGARs, please visit DPR's Reevaluation Web page at <http://www.cdpr.ca.gov/docs/registration/reevaluation/chemicals/sgars.htm>.

PRELIMINARY INVESTIGATIONS (EVALUATIONS)

DPR conducts preliminary investigations of products (and active ingredients) for which the Department, or other State or county agencies, have identified possible hazards. As a result of evaluation, the investigation may lead to formal reevaluation. No preliminary investigations are underway at this time.

For more information on this semiannual report or any of DPR's reevaluations, please visit DPR's Reevaluation Program Web page at <https://www.cdpr.ca.gov/docs/registration/reevaluation/reevals.htm> or contact either Ms. Denise Alder, Senior Environmental Scientist (Specialist), at Denise.Alder@cdpr.ca.gov or 916-324-3522 or Ms. Brittanie Clendenin, Environmental Scientist, at Brittanie.Clendenin@cdpr.ca.gov or 916-324-3896.

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